

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/478,262	Confirmation No. 2549
Applicants	:	Evert J. BUNSCHOTEN et al.	
Filed	:	May 25, 2004	
Title	:	PHARMACEUTICAL COMPOSITION FOR USE IN HORMON REPLACEMENT THERAPY	
Group Art Unit	:	1617	
Examiner	:	San Ming R. HUI	
Customer No.	:	28289	
Application No.	:	10/478,264	Confirmation No. 4962
Applicants	:	Evert J. BUNSCHOTEN et al.	
Filed	:	May 25, 2004	
Title	:	USE OF ESTROGEN COMPOUNDS TO INCREASE LIBIDO IN WOMEN	
Group Art Unit	:	1617	
Examiner	:	San Ming R. HUI	
Customer No.	:	28289	
Application No.	:	10/478,357	Confirmation No. 3771
Applicants	:	Evert J. BUNSCHOTEN et al.	
Filed	:	May 25, 2004	
Title	:	DRUG DELIVERY SYSTEM COMPRISING A A TETRAHYDROXYLATED ESTROGEN FOR USE IN HORMONAL CONTRACEPTION	
Group Art Unit	:	1617	
Examiner	:	San Ming R. HUI	
Customer No.	:	28289	

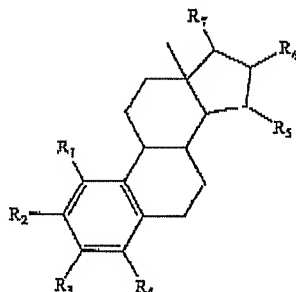
Application No.	:	10/517,509	Confirmation No. 1291
Applicants	:	Herman J. T. Coelingh Bennink et al.	
Filed	:	June 13, 2005	
Title	:	METHOD OF TREATING HUMAN SKIN AND A SKIN CARE COMPOSITION FOR USE IN SUCH METHOD	
Group Art Unit	:	1617	
Examiner	:	Samira JEAN-LOUIS	
Customer No.	:	28289	

DECLARATION

I, Strauss III, Jerome F. declare and state the following:

1. A detailed listing of my publications, together with details of my education, are given in my *curriculum vitae* which is attached as Exhibit A.
2. Based on my academic training and professional experience, I consider myself an expert in the field of estrogen-related therapies and treatments, and I was such a person in 2001 and 2002.
3. I have received copies of patent applications that I understand were filed in the United States and correspond to the above-captioned applications.
4. I understand that the above mentioned patent applications relate to:
 - new methods of contraception (Appln. 10/478,357);
 - new methods of hormone replacement therapy (Appln. No. 10/478,262);
 - a new method of increasing female libido (Appln. No. 10/478,264);
 - a new method treating vaginal dryness (Appln. No. 10/517,509).

The aforementioned methods have in common that they comprise administration of the following estrogenic component:



wherein R₁, R₂, R₃ and R₄ independently are a hydrogen atom, a hydroxyl group or an alkoxy group with 1-5 carbon atoms. R₅, R₆ and R₇ are hydroxyl groups. No more than three of R₁, R₂, R₃ and R₄ are hydrogen atoms. The invention also includes using variations of this formula, such as precursors capable of liberating a substance according to the aforementioned formula and mixtures of one or more of the aforementioned substances and/or precursors. One embodiment of the aforementioned formula is estetrol.

5. I have also received copies of Office Actions that have been issued in relation to the above referenced pending patent applications. Specifically, I have received copies of the following Office Actions:

- OA-1 - 10/478,262 (Non-final Office Action mailed on May 15, 2008)
- OA-2 - 10/478,264 (Non-final Office Action mailed on March 6, 2008)
- OA-3 - 10/478,357 (Non-final Office Action mailed on May 16, 2008)
- OA-4 - 10/517,509 (Non-final Office Action mailed on March 26, 2008)

6. I have further received copies of the following references that I have been told have been cited in the above mentioned Office Actions against the independent claims of the above referenced pending patent applications.

Publications mentioning estetrol:

- D1 US 5,211,952 (Spicer et al.) – cited in OA-4
- D2 US 5,340,584 (Spicer et al.) – cited in OA-2
- D3 US 5,340,586 (Pike et al.) – cited in OA-1, OA-2 and OA-3
- D4 US 2004/0192598 (Kragie) – cited in OA-4
- D5 Holinka, Biology of Reproduction, 1979; 20(2): 242-246¹ – cited in OA-1 and OA-2
- D6 Holinka, Biology of Reproduction, 1980; 20(4): 913-926² – cited in OA-1 and OA-2

Publications not mentioning estetrol:

- E1 Ullom-Minnich, American Family Physician, 1999; 60: 194-202 – cited in OA-1
- E2 Katzung, Basic and Clinical Pharmacology, 6th ed., 1995, 608-624 – cited in OA-3
- E3 Willhite et al. (Pharmacotherapy, 2001, vol. 21, issue 4, 464-480 – cited in OA-4
- E4 Sitruk-Ware et al. (Schweiz. Rundsch., Med. Praxis, 1997, vol. 86, No. 33, 1245-1248 – cited in OA-4

It is my understanding that the independent claims of the pending patent applications that are the subject of this Declaration were rejected as being unpatentable over the above cited references under 35 U.S.C. 103(a) (obviousness). I have been asked to comment on my understanding of the state of the art prior to June 11, 2002, which I understand is the priority date for Appln. No. 10/517,509. Particularly, I have been asked whether, prior to June 11, 2002, a person of ordinary skill in the art would have considered it obvious to use estetrol in the pharmacological applications listed in § 4. More particularly, I have been asked whether, prior to the June 11, 2002, a person of ordinary skill in the art would have been motivated to use estetrol in the pharmacological applications listed in § 4, and whether the discovery that estetrol was pharmacologically useful in these applications is unexpected and surprising.

7. It is my view that, prior to June 11, 2002, for the reasons presented below, a person of ordinary skill in the art would not have expected estetrol to be pharmacologically useable, and that the Applicants were the first to discover the pharmacological usefulness of estetrol. In addition, and more particularly, it is my opinion that, prior to June 11, 2002, a person

of ordinary skill in the art would not have expected estetrol to be pharmacologically active when orally administered.

8. I declare that before June 11, 2002 I had no knowledge of any concrete pharmacological application of estetrol. Furthermore, before June 11, 2002, I did not expect that estetrol can be used effectively as a drug in therapeutic treatments or in hormonal contraceptives. Based on the data from scientific literature that was available before June 11, 2002, I would have expected estrogenic activity of estetrol to be too low for pharmacological applications, such as the ones recited in Applicants' claims.

9. My view that a person of ordinary skill in the art would not have expected estetrol to be pharmacologically active is supported by leading textbooks in the field of endocrinology. In "Clinical Gynecologic Endocrinology and Infertility" ³ estetrol is solely mentioned in Chapter 8 (The Endocrinology of Pregnancy) under the subheading "Measurement of Estrogen in Pregnancy" (page 287) and in the index. On page 287 it is stated that "Estetrol (15alpha-hydroxyestriol) is formed from a fetal precursor and is very dependent on 15alpha-hydroxylation activity in the fetal liver. The capacity for 15alpha-hydroxylation of estrogens increases during fetal life, reaching maximum at term. This activity then declines during infancy and is low, absent or undetectable in adults. There is no clinical use for maternal blood or urine estetrol measurements during pregnancy. The clinical use of maternal blood and urine estetrol measurements is of no advantage over the usual estradiol assessment."

10. The unexpected pharmacological activity of estetrol is associated with Applicants' discovery that estetrol has a surprisingly long *in vivo* elimination half-life. Applicants' finding that estetrol has a terminal elimination half-life of about 28 hours, which is very much longer than that of the other pregnancy hormone estradiol (5-10 minutes), was very unexpected and provided the clue towards its pharmacological usefulness as will be further explained below.

11. It is my understanding that the claims of the pending patent applications that are the subject of this Declaration were rejected as obvious because it has been asserted by USPTO examiners that it is known from the references cited in § 6:

- (i) to use estrogens with or without progestins in HRT (reference E1);

- (ii) to use a combination of estrogen and progestin in hormonal contraceptives (reference E2);
- (iii) to use estrogen to treat decreased libido in women taking GnRH agonists (reference D2); and to use a combination of estrogen and androgen to treat decreased libido in oophorectomized women (reference D3);
- (iv) to treat vaginal dryness by administering estrogen (references D1, D4, E3, E4).

12. Assuming that the references cited by the USPTO examiners disclose the information contained in § 11 (i) to (iv), I do not think that, in view of these references, it would have been obvious to use estetrol in pharmacological applications described in § 4. I appreciate that the cited references D1 to D4 contain references to estetrol within a lengthy list of other estrogens. Furthermore, I have read the cited papers published by Holinka et al ("Holinka articles")^{1,2}, which report that parenterally administered estetrol produced estrogenic changes in the immature rat uterus.

13. I declare that although the cited references D1 to D4 list estetrol among candidate estrogens for pharmaceutical use, it is my view that a person of ordinary skill in the art having knowledge of the aforementioned patent publications D1 to D4 and the "Holinka articles", would not have expected estetrol to be pharmacologically useable for the reasons presented below.

14. The mere mentioning of estetrol in a long list of candidate estrogens in D1 to D4 without any experimental data to support the viability of pharmaceutical uses described in these patents, in my view would not have provided a person of ordinary skill in the art with any motivation to actually employ estetrol in these pharmaceutical uses. Furthermore, the aforementioned US patent publications would not have provided a person of ordinary skill in the art with any motivation to replace the estrogens employed in the uses (i) to (iv) mentioned in § 11 with estetrol.

15. In Holinka (1979)¹ the estrogenic activity of estetrol was evaluated by examination of uterine responses to subcutaneous administration of estetrol in doses of 10 and 50 µg/100g body mass. The effects were compared to those obtained by administration of 1 µg/100g body mass estradiol or estriol. The last paragraph of the abstract of Holinka (1979) reads as follows "It is concluded that estetrol administered as a single dose or in 2 doses at a 24 h interval

is a weak estrogen which produces effects of short duration. It cannot, however, be considered entirely devoid of estrogenic activity, even though true uterine hyperplasia, as estimated by DNA content, was not promoted by administration of the two 50 µg/100 g bw doses of estetrol”.

16. Holinka (1980)² describes the results of a study that aimed to extend the study described in Holinka (1979). In this follow-up study estrogenic effects on immature rat uterus of estetrol and the antiestrogen tamoxifen were compared with those of estradiol and estriol. This time, estetrol was injected subcutaneously for 3 days at a dose of 50 µg/100g body mass, a dose 50 times greater than the dosages of estradiol and estriol that were administered subcutaneously (at a dose of 1 µg/100g body mass). The last paragraph of the abstract of Holinka (1980) reads as follows: “In general estradiol treatment promoted the most marked changes, followed by tamoxifen, estriol and estetrol. On the basis of the present biochemical and morphological results, it is concluded that estetrol and tamoxifen have estrogenic effects on the immature rat uterus. However, the estrogenic potency of estetrol, relative to estradiol or estriol was low at the dosage and timing of administration used in these experiments; effects of estetrol introduced in the circulation at a constant rate were not evaluated. These results suggest that the conversion of estradiol to estetrol in the human fetus represent an efficient mechanism of inactivation of the placental hormone.” Specifically, even though Holinka et al administered 50 times more estetrol than estradiol or estriol, the observed uterotrophic effects of estetrol were still smaller than those of estradiol or estriol. Thus, from Holinka (1980), one of ordinary skill in the art would expect estetrol to be more than 50 times less effective than a weak estrogen, such as estriol.

17. It is my view that a person of ordinary skill in the art would have deduced from the Holinka articles that estetrol has estrogenic activity, but that it is a much weaker estrogen than the already weak estrogen estriol, given that estetrol injected subcutaneous at 50 µg/100g body mass exhibited less estrogenic activity than estriol injected subcutaneous at 1 µg/100g body mass. Estriol is a very weak estrogen due to its low receptor affinity in combination with its very short half-life of 5-10 minutes. Since the Holinka articles teach that estrogenic activity of estetrol is at least 50 times lower than that of a weak estrogen for which very few practical applications exists, the Holinka articles would not have provided a motivation for a person of ordinary skill in the art to investigate the potential pharmacological usefulness of estetrol.

18. Applicants have demonstrated that, contrary to what a person of ordinary skill in the art would have expected, estetrol is pharmacologically very active. The unexpected pharmacological activity of estetrol is associated with its surprisingly long *in vivo* elimination half-life. Whereas, under comparable conditions, the human estrogens estradiol and estriol have terminal elimination half-lives of about 30 minutes and 5-10 minutes respectively, estetrol has a terminal elimination half-life of about 28 hours. A person of ordinary skill in the art would have expected estetrol to be more comparable to estriol than estradiol given that (i) estetrol differs from estriol by only 1 hydroxy group and from estradiol by 2 hydroxy groups and (ii) both estriol and estetrol are produced during pregnancy. Hence, Applicants' finding that estetrol has a terminal elimination half-life that is 168-336 higher than that of the other pregnancy hormone estriol, was very unexpected and provided the clue towards its pharmacological usefulness. Based on my knowledge of the relevant art, I conclude that Applicants are the first to have discovered estetrol's pharmacological usefulness. As explained herein before, it is my view that, prior to June 11, 2002, a person of ordinary skill in the art would not have anticipated this usefulness.

19. In addition, I conclude that Applicants are the first to have discovered estetrol's high oral bioavailability. This finding is truly surprising as other human estrogens, notably estradiol, estriol and estrone, exhibit low oral bioavailability because they are largely metabolized into inactive metabolites during the so called "first pass" through the liver after oral administration. It is my opinion that, given that estetrol's estrogen receptor affinity was known to be considerably lower than that of estradiol and estriol, a person of ordinary skill in the art, being aware that known human estrogens are largely metabolized during the first pass, could not have anticipated the high oral bioavailability of estetrol. Thus, in my view, prior to June 11, 2002, a person of ordinary skill in the art could not have anticipated estetrol's oral pharmacological activity.

20. As mentioned herein before, it is my view that a person of ordinary skill in the art could not have anticipated the advantageous pharmacological properties of estetrol that Applicants have described in the above referenced pending patent applications and that have been reported in scientific articles that were published after June 11, 2002. In particular, such a skilled person could not have foreseen the favorable pharmacokinetic (ADME) and

pharmacodynamic properties of estetrol. These favorable properties of estetrol are remarkable since they are much less manifest in other human estrogens, notably estradiol, estriol and estrone. The unexpected favorable properties of estetrol that have been described by Applicants in the aforementioned pending patent applications and that were not known before June 11, 2003 include:

A. Long *in vivo* elimination half-life in the human

- In the first human study with estetrol, a dose-independent terminal elimination half-life of about 28 hours after single oral administration to early postmenopausal women was demonstrated ^{4,5}. Terminal elimination half-lives of the human estrogens estradiol and estriol under comparable conditions are about 30 minutes and 5-10 minutes respectively ³.

B. No binding affinity for sex hormone binding globulin (SHBG)

- Competitive ligand binding assays did not detect any binding of estetrol to the SHBG steroid-binding sites ^{4,6}. By contrast, estradiol is bound by SHBG with high affinity ⁶.

C. No ER α -mediated increase in SHBG production by HepG2 or Hep89 cells

- Fluorometric assays in wild-type human HepG2 and Hep89 cells showed that estetrol does not stimulate ER α -mediated increases in SHBG production by these cells, in contrast to estradiol and estriol ^{4,6}.

D. No conversion to other active metabolites

- Estetrol is an end-stage product of estrogen metabolism ^{4,5,7}. In contrast, especially after oral administration, estradiol is rapidly and reversibly converted by the liver to the estrogenic metabolites estrone and estrone sulfate.

E. No significant inhibition of P450 enzymes

- At a concentration of 10 $\mu\text{mol/l}$ estetrol has no inhibitory effect on any recombinant human P450 enzymes CYP1A2, CYP2C9, CYP2C19, CYP2D6 and CYP3A4. In contrast, at the same concentration estradiol moderately inhibits CYP1A2 and strongly inhibited CYP2C19 ^{4,7}.

F. Highly selective binding to estrogen receptors ER α and ER β

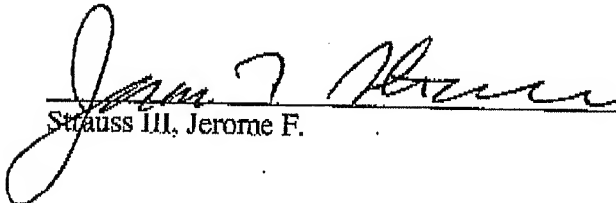
- Estetrol tested at a prime concentration of 10 $\mu\text{mol/l}$, did not show significant (>20%) inhibition of the binding of the respective ligands in 123 of the 124 assays studied (Estetrol only inhibited binding of prazosin at the adrenergic α_{1B} receptor by 23%) ^{4,7}.
- G. Estrogen agonist in bone, vagina, myometrium, endometrium and brain, but estrogen antagonist in breast tumor tissue in the presence of estradiol
- Estetrol significantly and dose-dependently inhibited the OVX-related increase in osteocalcin levels, increased bone mineral density and content, and increased bone strength ^{4,8}.
 - Estetrol is effective in preventing temperature rises dose-dependently in an animal model considered representative for menopausal vasomotor symptoms ^{4,9}.
In the modified Allen-Doisy test estetrol was found to have dose-dependent estrogenic effects on the vagina and on the uterus of ovariectomized rats including the endometrium ^{4,10}.
 - Estetrol at a twice-daily dose of 0.3 mg/kg and above effectively inhibited ovulation in regularly cycling female rats ^{4,11}.
 - Estetrol dose-dependently prevents the growth of chemically induced (DMBA) mammary tumors in rats and has the potential to reduce the number and size of pre-existing mammary tumors ^{4,12}. By contrast it is well-established that estradiol has proliferative effects on breast tumor cells and tissue.
- H. Oral absorption in the human with a strong dose-response relationship suggesting high oral bioavailability
- In a first-in-human study four single doses of 0.1, 1, 10 and 100 mg estetrol were administered orally to early postmenopausal women. High oral bioavailability, a strong dose-response relationship and a long elimination half life (see A) were found. For the first time (oral) pharmacodynamic effects of estetrol were observed since the data showed a strong suppression of follicle stimulating hormone (FSH) with the 100 mg dose and a dose-dependent inhibition of luteinizing hormone (LH) levels ^{4,5}.

The above mentioned features A to D imply that the estrogenic activity of estetrol is much more pronounced than could have been anticipated on the basis of the estrogen receptor affinity studies described in scientific literature before June 11, 2002. Features E and F indicate that it is unlikely

that estetrol administration will induce undesirable side-effects. Feature G indicates that estetrol may suitably be used as a drug in estrogen or hormone replacement therapy (ERT/HRT) including the prevention of osteoporosis (US 10/478,262), the treatment of female sexual dysfunction (US 10/478,264), topical treatment of vaginal atrophy (US 10/517,509) and as the estrogenic component in contraceptives (US 10/478,357). Feature H indicates that estetrol has potential as a once-a-day oral drug for human use.

21. I have not been compensated for the execution of this declaration, or any time I spent relating to this declaration.

22. I declare further that all statements made herein are true to my knowledge; and that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.


Strauss III, Jerome F. _____ Date 8/26/08

References

- ¹ Holinka et al., *In vivo effects of estetrol on the immature rat uterus*. Biol Reprod 20 (1979) 242-6.
- ² Holinka et al., *Comparison of effects of estetrol and tamoxifen with those of estradiol and estradiol on the immature rat uterus*. Biol Reprod 22 (1980) 913-26.
- ³ Leon Speroff, Robert H. Glass and Nathan G. Kase. *Clinical Gynecologic Endocrinology and Infertility*. Baltimore, Maryland, USA. Lippincott Williams & Wilkins, 1999.
- ⁴ Coelingh Bennink et al., *Estetrol Review: profile and potential clinical applications*, Climacteric 2008; 11 (Suppl 1): 47-58
- ⁵ Visser et al., *First human exposure to exogenous single-dose oral estetrol in early postmenopausal women*, Climacteric 2008; 11 (Suppl 1): 31-40
- ⁶ Hammond et al., *Estetrol does not bind sex hormone binding globulin or increase its production by human HepG2 cells*, Climacteric 2008; 11 (Suppl 1): 41-46
- ⁷ Visser et al., *In vitro effects of estetrol on receptor binding, drug targets and human liver cell metabolism*, Climacteric 2008; 11 (Suppl 1): 64-68
- ⁸ Coelingh Bennink et al., *Oral bioavailability and bone-sparing effects of estetrol in an osteoporosis model*, Climacteric 2008; 11 (Suppl 1): 2-14
- ⁹ Holinka et al., *Preventive effect of oral estetrol in a menopausal hot flush model*, Climacteric 2008; 11 (Suppl 1): 15-21
- ¹⁰ Heegaard et al., *Estrogenic uterovaginal effects of oral estetrol in the modified Allen-Doisy test*, Climacteric 2008; 11 (Suppl 1): 22-28
- ¹¹ Coelingh Bennink et al., *Ovulation inhibition by estetrol in an in vivo model*, Contraception 2008; 77: 186-190
- ¹² Coelingh Bennink et al., *Estetrol, a pregnancy specific human steroid, prevents and suppresses mammary tumor growth in a rat model*, Climacteric 2008; 11 (Suppl 1): 29

EXHIBIT “A”

VIRGINIA COMMONWEALTH UNIVERSITY- SCHOOL OF MEDICINE

CURRICULUM VITAE

JEROME F. STRAUSS, III

Home Address: 2805 Monument Avenue, Unit 3
Richmond, VA 23221

Office Address: Sanger Hall, Room 1-01
1101 East Marshall Street
Richmond, VA 23298-0565

Date of Birth: May 2, 1947
Place of Birth: Chicago, IL
Marital Status: Married 1970 - Catherine
Children: Jordan Lawrence, 1978
Elizabeth Johanna, 1981

Education:

1965-69	B.A.	Brown University
1969-74	M.D.	University of Pennsylvania
1970-75	Ph.D.(Molecular Biology)	University of Pennsylvania

Postgraduate Medical Training:

1975-76	Obstetrics and Gynecology Hospital of the University of Pennsylvania
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Faculty Appointments:

1976-77	<i>Associate</i> , Department of Obstetrics and Gynecology, University of Pennsylvania School of Medicine
1977-82	<i>Assistant Professor</i> , Department of Obstetrics and Gynecology, Pathology and Laboratory Medicine and Physiology, University of Pennsylvania
1982-85	<i>Associate Professor</i> , Department of Obstetrics and Gynecology, Pathology and Laboratory Medicine and Physiology, University of Pennsylvania
1985-	<i>Professor</i> , Department of Obstetrics and Gynecology, Pathology and Laboratory Medicine and Physiology, University of Pennsylvania
1987-	<i>Associate Chairman</i> , Department of Obstetrics and Gynecology, University of Pennsylvania
1992-2005	<i>Luigi Mastroianni, Jr. Professor and founding Director</i> , Center for Research on Reproduction and Women's Health

University of Pennsylvania

2005- *Dean, School of Medicine and Executive Vice President for Medical Affairs, and Professor of Obstetrics and Gynecology, Virginia Commonwealth University*

Hospital and Administrative Appointments (University of Pennsylvania):

1978-82	Medical Scientist Training Program Advisory Committee
1980-84	Clinical Research Center Advisory Committee
1981-87	Director, Endocrine Laboratory, Hospital of the University of Pennsylvania
1981-87	Principal Investigator, Institutional alpha fetoprotein screening program for neural tube defects
1982-	Member, Cancer Center
1983-90	Member, Long Range Planning Committee Subcommittee on Medical Education
1984-	Director, Division of Reproductive Biology Department of Obstetrics and Gynecology
1984-	Consultant, PMS Clinic, Department of Obstetrics and Gynecology
1984-89	Consultant, Women's Wellness Center
1985-86	Director, RIA Core Facility, Diabetes and Endocrinology Research Center
1985-86	Committee on AIDS
1985-86	Ad Hoc Committee on Animal Care Facilities
1985-89	Clinical Research Building Design Committee
1985-1993	Executive Committee, Graduate Group on Pathology
1986-	Diabetes Research Center Executive Committee
1986-1993	Director, Combined Degree Programs and Medical Scientist Training Program
1986-1993	Advisory Council, Biomedical Graduate Studies
1986-1993	Advisory Council, Medical Scholars Program
1987-1990	Member, Long Range Planning Committee
1987-1991	Member, Curriculum Committee School of Medicine
1987-1989	Member, Search Committee for the Chair of Physiology
1987-1989	Member, Search Committee for the Dean of the School of Medicine
1990	Acting Director, Biomedical Graduate Studies
1990-1993	Associate Dean for Combined Degree Studies and Special Research
1993-	Clinical Research Center Advisory Committee
1993-1995	Member, Committee on Appointments and Promotions, University of Pennsylvania Medical Center
1993	Executive Committee, Task Force on Women's Health Services
1995	Search Committee, Chair of Microbiology
1995	Task Force on human pre-embryo research
1996	Committee to review University policy on nepotism
1996-2002	Director, Center of Excellence in Women's Health
1996-	Penn-Hughes Scholars in Developmental Biology Advisor Committee
1996-	Director, National Cooperative Program in Infertility

	Research, University of Pennsylvania
1997	Search Committee, Chair, Department of Medicine
1998	Dean's Committee on the Life Sciences
1999-	International Programs Advisory Committee
1999	Committee to Review the Institute for Human Gene Therapy
1999-2002	Academic Review Committee, School of Medicine
1999	Chair, Committee to Review the Department of Genetics
2001	Human Subjects Research Committee
2001	Chair, Committee on Principles of Research Space Utilization

Hospital and Administrative Appointments (Virginia Commonwealth University)

2005-	Committee Member, Ex Officio, VCU Health System Authority
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Licensure: Pennsylvania, MD018395E

Hospital Staff Appointments

1981-2003	Hospital of the University of Pennsylvania
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Graduate Group Appointments at the University of Pennsylvania:

1978-2005	Physiology
1982-2005	Molecular Biology
1985-1996	Pathology (Executive Committee 1985-1992)
1988-2005	Cell and Molecular Biology

Awards, Honors and Membership in Honorary Societies:

1969	B.A. awarded cum laude with Honors in Biology
1969	New York City Health Sciences Training Program Fellowship
1971	Alpha Omega Alpha
1971-75	Medical Scientist Training Program Fellowship
1975	Rittenhouse Award, University of Pennsylvania School of Medicine
1979-	John Morgan Society, University of Pennsylvania
1983	Berwick Award for Distinguished Teaching
1983	Medical Student Government Distinguished Teaching Award
1990	Co-author Prize Paper, Society of Reproductive Endocrinologists, American Fertility Society
1990	President's Achievement Award, Society for Gynecologic Investigation
1992	Research Award, Society for the Study of Reproduction
1994	Institute of Medicine, National Academy of Sciences
1994	Transatlantic Medal, British Endocrine Society
2001	Beacon Award, Marine Biological Laboratories
2001	Society for Maternal-Fetal Medicine 2001 Award for Research Excellence (co-author best scientific paper)
2002	Fellow, International Academy of Human Reproduction
2004	Pioneer Award, Frontiers in Reproduction, Marine Biological Lab. And NICHD
2005	Distinguished Graduate Award, University of Pennsylvania School of Medicine
2006	Distinguished Scientist Award, Society for Gynecologic Investigation

2007	Distinguished National Research Service Award, Marine Biological Laboratories and NICHDF
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Named Lectureships

1985	James H. Leatham Memorial Lecturer, New Jersey College of Medicine and Rutgers University	
1989	Ernest W. Page Memorial Lecturer, University of	
1993	Thomas G. Muldoon Memorial Lecturer, Medical College of Georgia	
1994	Van Campenhout Memorial Lecturer, Canadian Fertility and Andrology Society	
1994	Maternal and Child Health Lecturer, Society for Perinatal Research	
1994	First Anita Payne Lecturer, University of Michigan	
1995	Serono Lecture, American Society for Reproductive	Medicine
1997	Earl R. Plunkett/Wyeth-Ayerst Lecture, University of Western Ontario	
1997	John Patrick Memorial Public Lecture, University of Western Ontario	
1998	Johns Hopkins-University of Maryland Lecture	
1998	Transatlantic Lecture, British Endocrine Societies	
1999	Dr. Jacob Probststein Visiting Professor, Washington University	
1999	A.V. Nalbandov Memorial Lecture, University of Illinois	
1999	The First Jordan M. Phillips Lecturer, American Association of Gynecologic Laparoscopists	
2003	Shirley Dungan Kheel Memorial Lecture, Eastern Virginia School of Medicine	
2003	Sydney A. Asdell Memorial Lecturer, Cornell University	
2005	Cosgrove Memorial Lecture, American College of Obstetricians and Gynecologists	
2006	Sidney Guzik Scholar Day Lecturer, University of Rochester	
2006	Sheldon Norsley III Memorial Lecture, Richmond Academy of Medicine	
2006	Ware-Dunn Lecture, Ware-Dunn Society	
2006	Van Campenhout Memorial Lecture, Canadian Fertility Society	
2007	Chuangkong Scholar, Chinese Ministry of education	

Memberships in Professional and Scientific Societies:

National Societies:

- Endocrine Society
 - Program Committee 1992-1994; Recent Progress in Hormone Research Steering Committee, 1995-1998
- American Physiological Society
- American Association of Pathologists
- Society for Gynecologic Investigation
 - Program Committee 1990, 1991
 - President nominee, 2001
 - President Elect, 2002
 - President, 2003

Society for the Study of Reproduction
 Nominating Committee, 1977;
 Membership Committee, 1982;
 Long Range Planning Committee, 1987;
 Director, 1988-1991;
 Program Committee, 1991-1993,
 Chair, Development and Endowment Committee, 1994 -1997
 Blue Ribbon Long Range Planning Committee, 1997
 American Fertility Society
 Chair, Postgraduate course, 1999
 Academy of Clinical Laboratory Physicians and Scientists

Local Societies:

Philadelphia Endocrine Society
 Board of Directors, 1978-1981
 Philadelphia Lipid Club

Editorial Positions:

1982-1986 Journal of Lipid Research, Associate Editor
 1986-1989& Endocrinology, Editorial Board
 1996-2000
 1986-1990 & Biology of Reproduction, Editorial Board
 1999-2003
 1987-1991 Journal of Lipid Research, Editorial Board
 1991-1999 Journal of Steroid Biochemistry and Molecular
 Biology, Corresponding Editor
 1992- Journal of Women's Health, Editorial Board
 1992- Steroids, Editor
 1993- Journal of the Society for Gynecologic Investigation,
 Editorial Board
 1993- Journal of Reproduction and Development,
 Special Advisory Board
 1996-1998 Placenta, Editorial Board
 1997 Encyclopedia of Reproduction, Associate Editor
 1997-2000 Endocrinology, Editorial Board
 1999- Trends in Endocrinology and Metabolism, Editorial Board
 1999- Reference en Gynecologie Obstetrique, Scientific
 2000- Seminars in Reproductive Medicine, Editorial Board
 2000- Journal of Endocrinology, Editorial Board
 2000-2005 Human Reproduction Update, Associate Editor
 2004- Science, Board of Reviewing editors
 2007- Molecular Human Reproduction, Associate Editor

Service for the National Institutes of Health and National Science Foundation:

1981 Ad hoc member, Biochemical Endocrinology Study
 Section, NIH
 1983-1987 Member, Biochemical Endocrinology Study Section,
 NIH
 1983 Consultant, National Science Foundation,
 Regulatory Biology
 1983 Special Reviewer, Endocrinology Study Section, NIH
 1984 Member, Special Study Section for review of
 proposals on human infertility
 1988 Member, Special Study Section for review of
 Medical Scientists Training Programs

1988-1992 Member, Population Research Committee, NICHD
 1989-1992 Chair: Population Research Committee, NICHD
 1991 Co-Chair, Early Development Working Group, Office of
 Research on Women's Health
 1992 Ad Hoc Member, Maternal and Child Health Committee, NICHD
 1992 NIEHS Contracts Review Committee
 1993- International Cooperative Programs Study Section
 1994 NIDA Contract Review Committee
 1995 Chair, Conference on establishing an Americas
 Reproductive Sciences Network
 1995- Chair, Reproductive Scientists of the Americas Network
 1996 Chair, N.I.C.H.D. Special Study Section for Center grant
 review
 1996- Co-chair Indo-U.S. joint Working Group on Contraception
 1997 Special reviewer, HED-1 Study Section
 2000 Special reviewer, ENDR-2G1 Study Section
 2001 Chair, ENDR-2G1 Study Section
 2002 Member, ENDR-2G1 Special Emphasis Panel
 2002- National Child Health and Human Development Advisory Council
 2003 Chair, Institute of Medicine Committee on Frontiers in Contraception
 Research

Other service activities:

1983- Consultant, Medical Research Council of Canada,
 Grant Review
 1983- Consultant, Veterans Administration, Division of
 Research Grants
 1983 Review Committee for Middle States
 Accreditation, Department of Biochemistry and
 Physiology, Medical College of Pennsylvania
 1983-1985 Consultant, Corning Medical, on development of
 diagnostic reagents
 1983 Consultant, Wyeth Pharmaceutical Co., on
 development of diagnostic reagents
 1983 Inspector, College of American Pathologists,
 Laboratory Standards
 1984 Co-organizer, Symposium on Lipoprotein and Cholesterol Metabolism in
 Steroidogenic Tissues, Quebec, Canada
 1984- Consultant, United States-Israel Binational
 Agricultural Research Development Fund, Grant review
 1985-1986 Consultant, Baker Instruments, on development of
 diagnostic reagents
 1986 International Organizing Committee, 1st International Symposium on
 Ovarian Function, Sapporo, Japan
 1987 International Organizing Committee, Workshop on
 Maternal Recognition of Pregnancy, Jerusalem, Israel

 1988-1994 Board of Directors, Ovarian Workshops
 1989 Institute of Medicine, National Academy of Sciences
 1990 Advisory Group on Assisted Reproductive Technologies
 1991 International Organizing Committee, IInd International
 1992 Symposium on Ovarian Function, Sapporo, Japan
 1990 Co-organizer, Workshop on Uterine and Embryonic factors in
 Early Pregnancy, Bellagio, Italy

1991	External Consultant, Review of the Department of Ob/Gyn, Yale University
1991-1993	Scientific Advisory Committee VIIIth World Congress on In Vitro Fertilization and Alternate Assisted Reproduction, Kyoto, Japan
1991-	Scientific Advisory Committee, Wisconsin Regional Primate Center
1991	Organizing Committee Symposium on Endocrinology of Embryo-endometrial interactions, Bordeaux, France
1991	Institute of Medicine, National Academy of Sciences Committee on Research in Academic Departments of Obstetrics and Gynecology
1991-	Reproductive Scientist Training Program, Evaluation and Selection Committees
1992-1995	Ares-Serono Scientific Advisory Board in Reproductive Endocrinology
1993	Scientific Committee, Second International Conference on the Endometrium
1994	Organizing Committee, 3rd International Symposium on Ovarian Function, Sapporo, Japan
1994	Board of Directors, World Congress on Human Reproduction
1994-	External Advisory Board, University of Pittsburgh Center for Reproductive Biology
1994-1996	Scientific Advisory Board, Biointerventions Inc.
1994-1997	NIDA Advisory Committee for University of Kansas Contract on Placental Drug Transfer
1995	Consultant, Akzo-Nobel, Organon Pharmaceutical Co.
1996-1999	Chair, Scientific Advisory Board, Reprogen Inc.
1996-	Advisory Committee, Burroughs-Wellcome Fund Career Awards (Co-Chair 2000-)
1996-	Advisory Board, Perinatology Research Center, Brown University
1997	Organizing Committee, FASEB Conference on fetal vascular physiology
1997-1998	Member, Item-writing Committee, USMLE
1997-2001	Expert Advisory Panel, FIGO
1997-	Advisory Committee, University of Maryland Reproductive Sciences Center
1997	Chair, External Advisory Board, Northwestern University Center for Reproductive Sciences
1997-	Chair, Scientific Advisory Board, Femme Pharma, Inc.
1998	Scientific Advisory Committee, IVth Sapporo Ovary Symposium
1998-2002	N.V. Organon, Medical Advisory Board
2000-2002	Scientific Advisory Board, GeneFormatics, Inc.
2000	Co-organizer, Society for Gynecologic Investigation Symposium on Biotechnology in the Service of Reproductive Medicine, Salt Lake City, UT
2000-2002	Scientific Advisory Board, DIOGENICS/PLUVITA
2000	Scientific Organizing Committee, Serono Workshop on Reproductive Competence, Santiago, Chile
2000	Scientific Organizing Committee, Serono Symposium on Human Implantation, Madrid, Spain
2000-	Chair, External Advisory Board, K-BRIN, State of Kansas Research Consortium
2001	Co-organizer, 2nd International Workshop on Human Human Implantation, Madrid, Spain
2002	Scientific Advisory Committee, Vth Sapporo International Symposium on

	Ovarian Function
2002	Centocor, Clinical Advisory Board on Endometriosis
2002-	Serono, Consultant on clinical applications of recombinant LH
2002-	Board of Directors, Burroughs Wellcome Fund (Executive Committee: 2004-)
2003-	Ortho-McNeil, Consultant
2003	External Review of the Baker Institute, Cornell University
2004-	Scientific Advisory Board, Specialty Laboratories
2004	Review of the Center for Reproduction Research, Columbia University
2004-	Consultant, Serono Foundation
2005-	Berlex Foundation, Board of Trustees
2005	Reviewer, NIEHS Intramural Programs in Reproduction, Board of Scientific Councillors
2006	Ad Hoc Study Section, NIH Director's Awards
2007	Reviewer, Board of Scientific Counselors, NICHD Intramural Programs

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3. Kraicer, P.F., Strauss, J.F. III: Ovulation block produced by an inhibitor of luteotropin, ergocornine. *Acta Endocrinologica* **65**: 698, 1970.
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5. Strauss, J.F. III, Stambaugh, R.L.: Ovarian dehydrogenase activities during pregnancy in the rabbit. *Proceedings of the Society of Experimental Biology and Medicine* **140**: 1143, 1972.
6. Strauss, J.F. III, Mastroianni, L. Jr., Stambaugh, R.L.L.: Human ovarian enzymes during pregnancy. *Journal of Clinical Endocrinology and Metabolism* **36**: 192, 1973.

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12. Strauss, J.F. III, Flickinger, G.L.: Phospholipid metabolism in cells from highly luteinized rat ovaries. *Endocrinology* **101**: 882, 1977.
13. Addonizio, V.P., Strauss J.F. III, Macarak, E., Coleman, R.W., Edmunds, H.L.: Preservation of platelets with prostaglandin E1 during total cardiopulmonary bypass in rhesus monkeys. *Surgery* **83**: 619, 1978.
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"Labor Biomarkers" (J.F. Strauss, III, A. Brown, R.S. Leite, M.D. Sammel) United States Patent Application No. 60/646,589 submitted January 26, 2005, patent pending.

"Ectopic Pregnancy Markers" (G.L. Gerton, Kurt T. Barnhart, M, Sammel, J.F. Strauss, III) United States Patent Application submitted December 22, 2004.

"Genetic Markers for Assessing Risk of Premature Birth Resulting from Preterm Premature Rupture of Membranes (J.F. Strauss, III and H. Wang) United States Patent Application 11/734,383 submitted, April, 2007.

Principal Investigator of Current Grants

R01 HD34612
TDC \$785,000

Mechanisms of Fetal Membrane Rupture

9/1/08-12/31/11

R01 HD37416 TDC \$1,250,000	Molecular Basis of Human Sperm Motility	4/1/00-3/31/011
March of Dimes Genetics of preterm birth TDC \$501,000		4/1/05-3/31/09
K12HD05581 TDC \$2,400,000	VCU Building Interdisciplinary Research Careers in Women's Health	10/1/07-7/30/12
P60MD002256 TDC \$4,200,000	National Center on Minority Health & Heath Disparities	10/1/07-7/31/12